

REMARKS

The as-filed abstract has been replaced to avoid Examiner's objection to the single sentence claim structure.

Claims 1-44 are pending. No claims have been cancelled or withdrawn.

The undersigned is appreciative of the Examiner's conclusion that claims 13,14,19-21 and 25-37 are allowable if rewritten in independent form and amended to overcome section 112, second paragraph issues.

Support for the amendment to claims 8, 9, and 11 is found in as-filed claim 1. Support for the amendment to claims 12, 13, 14, and 18 is found in as-filed claim 11. Support for the amendment to claim 19 is found in as-filed claim 18. Support for the amendment to claim 27 is found in as-filed claim 11. Support for the amendment to claims 28, 29, and 31-37 is found in as-filed claim 27. Support for the amendments to claim 38 is found in the as-filed specification at page 7 lines 27-29, and at page 8, lines 7-8. Support for the amendment to claim 39 is found in the as-filed specification at page 10 lines 10-19 and as-filed claim 38. Support for the "wherein the intermediate base portion is connected only to the upper and lower shaving portions" amendment to claim 43 is found in the as-filed specification at page 6 lines 21-26 and in as-filed Figure 4a. Support for the "wherein each of the upper and lower portions has an inner and an outer surface, and wherein the outer surface of each of the upper and lower portions is smooth" amendment to claim 44 is found in the as-filed specification at page 7 lines 27-31 and page 8 lines 1-6 as well as in as-filed Figure 8. Support for the limitation "wherein the inner and outer surfaces on the upper and lower portions form a tip suitable for shaving endplates" is found at page 7, lines 30-31. Support for the "constant width" limitation is found in Figure 8.

Claims 8-14, 18, 19, and 27-40 stand rejected under 35 USC 112, second paragraph as being indefinite.

In claims 8-9, the Examiner states that, in line 1, it is unclear how the base “upper” and “lower” portions relate to those already set forth in the parent claim 1. Applicants have deleted the reference to the base further comprising “upper” and “lower” portions in these dependent claims, as the Examiner pointed out these are already recited in the base portion of parent claim 1. As claim 10 depends from claim 9 which has been amended to overcome the Examiner’s section 112 rejection, the amendment to claim 9 also overcomes the Examiner’s rejection of claim 10.

In claim 11, the Examiner states that it is unclear how the base “upper portion” and base “lower portion” relate to the structures having the same name and already set forth in parent claim 1. Applicants have amended claim 11 to delete the reference to the base “further comprising” these portions, and to make it clear the upper and lower portions of the base are the same structures recited in parent claim 1.

In claims 12-14 the Examiner finds that there is insufficient antecedent basis for the I-beam-like shape. Applicants have amended these claims to depend from claim 11, which recites an I-beam-like shape.

Examiner also found the limitation in claim 12 of “I-beam-like shape includes an I-beam shape” to be confusing and not understood. Applicants submit that the reference to an “I-beam-like shape” is intended to be broader and encompass variations upon the classical I-beam shape which is shown in Figure 4A. As-amended Claim 12 requires the classical I-beam shape of Figure 4A, and not variations of the classical I-beam shape (as shown in Figures 4B and 4C).

In claim 18, the Examiner takes the position that there is no antecedent basis for “the intermediate base portion”. Applicants have amended claim 18 to clarify that portion and to provide dependence from claim 11, thereby providing the necessary antecedent basis for the intermediate portion of the base.

In claim 19, the Examiner takes the position that there is no antecedent basis for the plural “secondary orthogonal shavers”. Applicants have amended claim 19 to provide the proper antecedent basis.

In claim 27 the Examiner takes the position that there is no antecedent basis for “the intermediate extending portion”. Applicants have amended the claim to eliminate the “extending” description, and to depend from claim 11.

In claim 32, line 1 the Examiner takes the position that there is no antecedent basis for “the taper distal section”. Applicants have amended the claim to depend from claim 31 which provides the antecedent basis for the “tapered distal portion”.

In claims 28-37, the parent claim 27 refers to a “neck portion” and a “head portion”, the Examiner points out that the dependent claims all refer to these structures simply as the “neck” and “head” and encourages that consistent terminology be used. Applicants have followed the Examiner’s suggestion and amended claims 28-37 to refer to “neck portion” and “head portion” to be consistent with the parent claim 27.

In claims 38-40, the Examiner points out that the limitation in claim 38 that the shaving portion has a vertically extending portion that can apparently be no extending portion (0% and dependent claim 40) is confusing and apparently meaningless. Applicants have removed the “vertically extending portion” limitation from claim 38 and added it to the dependent claim 39 to further describe the shaving portion as including a vertically extending portion extending toward the opposite shaving portion for a distance of “up to 30%” of the separation distance. Applicants submit that new wording of this limitation requires the presence of a vertically extending portion and so does not include a 0% separation distance. These amendments also clarify the original claim 40 language.

The Examiner has rejected claims 1-12, 15, 18, 22-24 and 38-44 pursuant to 35 USC 102(a) as being anticipated by US Patent No. 5,649,945 (Ray et al.). The Examiner concludes that the structure identified in Ray et al Figure 8 has no ascertainable structural

distinctions from Applicants' claimed device other than Applicants' intent that the tool be used in a horizontal position rather than a vertical position. Applicants respectfully disagree.

Independent claims 1, 38, 41, and 42 each recite a vertebral endplate chisel having a guide located between upper and lower shaving portions. A guide is a non-cutting member that helps align the chisel if the chisel were somehow misaligned, thereby insuring that equal amounts of material are removed from the upper and lower workpiece portions. Ray does not teach or suggest any type of guide. To the contrary, Ray describes a knife blade for cutting flaps in the annulus tissue. The blade has a horizontal member 70 extending in a triangular fashion from the base with a sharp tip 76 on the end for piercing the annulus tissue. Two vertical members 72a, 72b on either side of the horizontal members create vertical cuts in the annulus tissue resulting in an elongated H-style cut. The horizontal member is not used as a guide but to create a desired cut in the tissue to provide access to the nucleus inside. Since the horizontal member of Ray will simply cut through tissue, it will not help re-align a misdirected tool nor insure proper material removal, and so it is not a guide. Accordingly, since claims 1, 38, 41 and 42 are not anticipated by but rather are patentably distinguishable from Ray et al., the present rejection over Ray should be withdrawn.

Claims 2-12, 15, 18, 22-24 all depend directly or indirectly from independent claim 1 which applicants submit are patentable based on the arguments presented above. Therefore, the rejection of these claims in view of Ray should be withdrawn as well.

Independent claim 43 recites a vertebral endplate chisel having a base with upper and lower shaving portions and an intermediate portion narrowing distally to form secondary orthogonal shavers trailing the upper and lower shaving portions. The Examiner suggests, that if Ray's device is used such that its base portions are in a horizontal position then it is the same as the Applicant's device and anticipated by Ray. Applicants respectfully submit that claim 43 as amended is patentable over Ray. If, as the Examiner suggests, Ray's tool were to be turned and used such that the upper and

lower portions are horizontal, then the intermediate portion which extends beyond the upper and lower portions will be the first portion to create a vertical cut followed by horizontal cuts made by the upper and lower portions. Simply, the intermediate portion of Ray does not trail the upper and lower portions.

The Applicants' secondary orthogonal shavers are provided in a trailing location because they are meant to break up pieces of bone that have been shaved off the endplates, not to provide an additional cut between the upper and lower portions. In addition, use of the Ray device as suggested creates an I-shaped cut. In contrast, Applicants' device as described in claim 43 will not create an I-shaped cut because its upper and lower portions will create the first horizontal cuts, followed by the secondary orthogonal shavers which extend only part way and therefore cut only part way between the upper and lower portions. This is important difference because Ray's device is cutting flaps in an intact annulus and Applicants' device is shaving bone off the endplates of a vertebral body. For these reasons, the rejection of claim 43 in view of Ray should be withdrawn.

Independent claim 44 has been amended to recite that the width of the upper and lower portions is constant. In contrast, the width of the upper and lower portions of the Ray device tapers. This is an important distinction as the Applicants' device is intended for shaving vertebral body endplates, and so the upper and lower portions need to have a constant width so that the surface can create an even cut. In contrast, since the Ray device is used to create flaps in the annulus, it needs to have a taper to penetrate the tissue and create the flap. For these reasons, the rejection of claim 44 in view of Ray should be withdrawn.

Claim 43 also stands rejected under 35 USC 102(e) as being anticipated by Nicholson et al (US 6,241,733). Claim 43 has been amended to state that the intermediate base portion is connected only to the upper and lower portions. In contrast, vertically-disposed intermediate portion 64 in Nicholson et al is also connected to a third middle horizontal member. As stated in the specification of Nicholson et al at col. 13

lines 48-50, the Nicholson device is designed to capture the bone that is split within the cavities of the device for later use. In contrast, Applicants' device is designed to direct the shaved bone towards downstream debris pathways. Accordingly, since Applicants' device does not contain the shaved bone, it does not need (nor would it want) the third horizontal member between the upper and lower shaving portions of the device. For these reasons, the rejection of claim 43 in view of Nicholson should be withdrawn.

Claim 44 is rejected under 35 USC 102(b) as being anticipated by Japanese patent 210316, specifically figure 8. The device shown in Figure 8 is a rasp that is used to cut bone by pushing the rasp back and forth. The ridges on the outer surface of the upper and lower portions of the rasp cut the bone into chips. Applicants have amended claim 44 to state that the outer surfaces on the upper and lower portions of their device are smooth. The cutting action of Applicants' claimed device is provided only at the sharp tips formed between the smooth outer and inner surfaces of the upper portion and the lower portion. The outer surface of the claimed invention does not cut the bone, as does the outer surface of the rasp of the cited Japanese patent. For these reasons, the rejection of claim 44 in view of the Japanese patent should be withdrawn.

Dependent claims 16 and 17 are rejected under 35 USC 103(a) as being unpatentable over Ray et al (US 5,649,945). The Examiner states that the claimed angles would fall well within a range one of ordinary skill in the art would have found obvious. Since claims 16 and 17 depend indirectly from claim 1 which includes a guide located between the shaving portions of the instrument, and since claim 1 is patentable over Ray as discussed above, the claims depending from claim 1 are also patentable. For these reasons, the rejection of claims 16 and 17 in view of Ray should be withdrawn.

Applicants believe that inventorship remains the same as in the as-filed case.

In addition, please provide any extensions of time which may be necessary and charge any fees which may be due to Deposit Account No. 10-0750, but do not include any payment of issue fees.

Should there be any remaining or further questions, the Examiner is requested to place contact the undersigned directly.

Respectfully submitted,

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